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Motions, Pleadings and Filings

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United States District Court, E.D. Pennsylvania.
In re: DIET DRUGS (PHENTERMINE, FENFLURAMINE, DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION
No. MDL 1203.

June 20, 2000.

Gregory P. Miller, Miller, Alfano & Raspanti, P.C., Phila.

Nina M. Gussack, Pepper, Hamilton & Scheetz, Michael T. Scott, Reed, Smith, Shaw & MC Clay, Arnold Levin, Levin, Fishbein, Sedran & Berman, Edward W. Madeira, Jr., Pepper, Hamilton & Scheetz, Philadelphia, for in re: Diet Drugs (Entermine, Fenfluramine, Dexfenfluramine) Products Liability Litigation.

MEMORANDUM AND PRETRIAL ORDER NO. 1332

BECHTLE, J.

***1** Presently before the court are American Home Products Corporation's Motions to Limit the Expert Testimony of Jerome L. Avorn, M.D. and to Exclude Testimony of Lewis J. Rubin, M.D. and the responses thereto. For the reasons set forth below, the court will grant the motions in part and deny them in part.

I. *BACKGROUND*

Plaintiffs have offered Jerome L. Avorn, M.D. and Lewis J. Rubin, M.D. as expert witnesses in several civil actions in this MDL No. 1203. Primarily, their testimony will cover issues about the health risks and benefits of the diet drugs Pondimin [FN1] and Redux. [FN2] AHP challenges several of the opinions to be offered by these physicians. The court will address the background of these challenges for each physician separately.

FN1. Pondimin is the brand name for the diet drug fenfluramine.

FN2. Redux is the brand name for the diet drug dexfenfluramine.

A. *Jerome L. Avorn, M.D.*

Dr. Avorn is being offered as a generic liability expert in these proceedings. He is a medical doctor, a pharmacoepidemiologist [FN3] and a pharmacoeconomist. [FN4] Dr. Avorn is highly qualified in these areas of expertise, as borne out by his curriculum vitae. (Pls.' Opp. to AHP Mot. re: Avorn Ex. A.) Nonetheless, AHP argues that Dr. Avorn lacks the qualifications and reliable methodology to offer many of the opinions he expresses. AHP asserts that Dr. Avorn's testimony as regards the weight of evidence, the intent of AHP and his personal interpretation of documents and testimony are simply not expert testimony. AHP challenges seven areas of testimony to be offered by Dr. Avorn.

FN3. Pharmacoepidemiology is the science that applies epidemiologic approaches to studying the use, effectiveness, value and safety of pharmaceuticals. (AHP Mot. re: Avorn at 2.)

FN4. Pharmacoeconomics is the study of the relationship between a drug's benefits and its risks and costs. (Pls.' Opp. to AHP Motion re: Avorn at 2.)

1. Opinions about the Labeling of Pondimin and Redux.

Dr. Avorn testified that between 1987 and 1996, the Pondimin warning concerning pulmonary hypertension was false and misleading and that it was inadequate. (AHP Mot. re: Avorn Ex. A at 46-53.) He also testified that he would have preferred that the labeling for Pondimin and Redux in 1996 and 1997 had been formatted to place information about pulmonary hypertension in a black box rather than bolded text not in a box. *Id.* at 55-56; 97. Dr. Avorn also endorsed the boxed format adopted by the French government. *Id.* at 88-91.

AHP asserts that Dr. Avorn is not an expert regarding FDA drug labeling regulations and that, in

fact, he has disclaimed that he is an expert concerning regulations governing pharmaceutical labeling. (AHP Mot. re: Avorn Ex. B at 46.) AHP further asserts that even if Dr. Avorn were qualified, there is no indication of any systemic review of the evidence concerning AHP's labeling, and thus, there is no reliable methodology underlying Dr. Avorn's opinion.

Plaintiffs respond that Dr. Avorn is not being offered as an expert in FDA regulations. According to Plaintiffs, what is at issue in this litigation is whether AHP adequately warned physicians and patients about the risks of Pondimin and Redux, not whether AHP complied or did not comply with FDA regulations. Plaintiffs argue that even if AHP did comply with the FDA regulations, that would not be dispositive of whether it satisfied its duty under the common law. Plaintiffs assert that Dr. Avorn's testimony goes to the issue of whether the drug labels were *actually* false and misleading, and not just in the regulatory sense. [FN5] In addition, Plaintiffs argue that Dr. Avorn's opinions are all grounded in facts and evidence that will be introduced. [FN6]

> FN5. AHP objects to Dr. Avorn's testifying as to whether the Pondimin labeling regarding pulmonary hypertension was "false and misleading" because those terms are standards under FDA regulations for determining whether a pharmaceutical product is misbranded. 21 C .F.R. § 201.56. (AHP Mot. re: Avorn at 14.) Plaintiffs response is that Dr. Avorn is not being offered to testify as an expert in FDA regulations. Instead, his testimony on this subject refers only to the ordinary meaning of the words "false" and "misleading." (Pls .' Opp. to AHP Mot. re: Avorn at 11.)
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> FN6. For example, Dr. Avorn opines that AHP should have included a black box warning about primary pulmonary hypertension ("PPH"). According to Plaintiffs, that opinion is grounded in evidence which will demonstrate that AHP knew of more cases of PPH than indicated on the original warning, that the French government required a black box warning for dexfenfluramine and that an FDA officer indicated that Redux should have a black box warning.

2. Speculation as to AHP's Motives and Intent in Marketing and Labeling Pondimin and Redux.

***2** Dr. Avorn opines that AHP's failure to change the Pondimin label concerning pulmonary hypertension and in drafting the Redux label with the FDA was driven by its desire to increase profits. (AHP Mot. re: Avorn Ex. A at 94.) AHP asserts that this amounts to improper lay opinion testimony, that Dr. Avorn lacks personal knowledge concerning AHP officials' thought processes and that his opinions of AHP's corporate intent invade the province of the jury. AHP also argues that the true purpose of Dr. Avorn's testimony is to place an expert's stamp of approval on Plaintiffs' interpretation of the evidence.

Plaintiffs respond that Dr. Avorn's testimony about the risks, benefits, patterns of use and economics of Pondimin and Redux is within the scope of his expertise as a pharmacoeconomist and pharmacoepidemiologist and is based on AHP internal documents relating to marketing and sales.

3. Speculation as to the Thoughts and Expectations of Physicians.

Dr. Avorn has given opinions regarding the thoughts and expectations of physicians with respect to their decisions to prescribe Pondimin and Redux and their interpretations of prescription drug labels and warnings. (AHP Mot. re: Avorn Ex. A at 35-39 and 85-86.) AHP asserts that these opinions are not based on any sort of survey or comparative analysis and instead appear to be an inappropriate attempt to convert Dr. Avorn's subjective views into expert opinion.

Plaintiffs respond that Dr. Avorn is qualified to provide opinions to the jury about what information physicians expect to be provided in drug labeling and their decision making process in prescribing drugs. In fact, Plaintiffs assert that Dr. Avorn's qualifications show that he is integrally involved in the choice of all drugs to be used for an entire teaching hospital at Harvard Medical School. (Pls.' Opp. to AHP Mot. re: Avorn Ex. A.)

4. Dr. Avorn's Recounting of Various Documents or Testimony.

Throughout his preservation deposition testimony, Dr. Avorn read into the record the content of other documents or testimony. AHP asserts that Dr. Avorn lacks personal knowledge of these matters and that Plaintiffs cannot use him as a funnel for a broad range of documents and testimony about which he has no knowledge or legitimate expert opinions.

Plaintiffs respond that Dr. Avorn's testimony recounting various documents is merely laying the foundation for his opinions.

5. Dr. Avorn's Reaction to Documents Discussing the Approval Process for Redux.

Throughout his preservation deposition testimony, Dr. Avorn is asked to give his reaction to certain documents discussing the approval process of Redux. AHP asserts that Dr. Avorn has no personal knowledge of these documents and that his reactions are not expert opinions as Dr. Avorn is not an expert in drug approval. AHP argues that insofar as Dr. Avorn's reaction is that he would have acted differently than AHP or the FDA, such opinion is speculation and invades the province of the jury. Plaintiffs respond that Dr. Avorn is generally qualified to testify about prescription drug policy issues.

6. Dr. Avorn's Speculation Regarding the Processing of Certain Adverse Drug Experience Reports and AHP's Intent in Processing and Investigating Adverse Drug Experience Reports.

***3** Dr. Avorn gave testimony in his preservation deposition concerning how he would have processed certain adverse drug experience reports differently than AHP and that the way AHP handled these reports was motivated by a desire to mislead the public regarding risks associated with Pondimin and Redux. (AHP Mot. re: Avorn Ex. A at 38; 127-35; 144-45.) AHP asserts that Dr. Avorn is not an expert in investigating or processing adverse drug event reports and his speculations about AHP's intent are for a jury, not an expert, to evaluate. Plaintiffs respond that, as a pharmacoepidemiologist, Dr. Avorn is qualified to testify about how post-marketing reports of adverse reactions should be evaluated.

7. Dr. Avorn's Agreement with Colin Bloor, M.D.'s Opinion Regarding Pathology Slides from an Animal Study on Dexfenfluramine.

At his preservation deposition, Dr. Avorn testified that he agreed with Colin Bloor, M.D., a pathologist who reviewed rat slides from a Les Laboratories Servier ("Servier") study and opined that the results from that study mandated further investigation into the risks involved with dexfenfluramine. (AHP Mot. re: Avorn Ex. A at 104-05.) AHP asserts that Dr. Avorn has no expertise in pathology, which is the subject matter of Dr. Bloor's opinion, and that he has not reviewed the materials cited by Dr. Bloor. Plaintiffs respond that Dr. Avorn refers to this study only in the sense that it should have put AHP on notice that fibrotic heart conditions (such as valvular heart disease) were a potential problem with Redux.

B. *Lewis J. Rubin, M.D.*

Dr. Rubin is among a handful of internationally recognized authorities on PPH and its relationship to diet drugs. He is highly qualified in his field, as borne out by his curriculum vitae. (Pls.' Opp. to AHP Mot. re: Rubin Ex. 14.) Nonetheless, AHP argues that Dr. Rubin lacks the qualifications and reliable methodology to offer many of the opinions he expresses. AHP challenges three areas of testimony purported to be offered by Dr. Rubin. [FN7]

> FN7. AHP asserts as a fourth ground that Dr. Rubin should not be allowed to rely on data from the Surveillance of North American Pulmonary Hypertension ("SNAPH") Study (which he participated in) when the study data have not been produced. AHP is currently pursuing these documents pursuant to Hague Convention Rules. To the extent that AHP asserted this ground for exclusion in its motion, it is now moot.

1. Opinions Related to Pondimin Labeling.

Dr. Rubin opines that between 1994 and 1996, the Pondimin label relating to pulmonary hypertension incorrectly stated the number of known cases of PPH associated with fenfluramine, and fails to distinguish between pulmonary hypertension ("PH") and PPH. [FN8]

> FN8. According to Dr. Rubin, PH is not necessarily progressive and fatal and can be treated by addressing the underlying condition that caused elevation of the pulmonary artery pressures in the patient. (AHP Mot. re: Rubin Ex. A ¶ 25(d).) On the other hand, PPH is a rare and difficult condition to diagnose, and it is also a progressive and incurable condition. (AHP Mot. re: Rubin Ex. A ¶ 25(d).)

AHP asserts that Dr. Rubin is not qualified to opine on the adequacies of the Pondimin label, that he is not an expert in warnings and that he has no expertise regarding the regulatory aspects of drug warnings. AHP further asserts that even if Dr. Rubin's basis for his opinion is only as a practicing physician, that is

not a sufficient basis to offer opinions on drug labeling.

AHP argues that Dr. Rubin's opinions about the Pondimin label amount to nothing more than personal opinion of what he thinks is AHP's ethical responsibility. AHP asserts that this opinion is not based on any type of methodology and thus does not constitute scientific, technical or other specialized knowledge. In support of its argument, AHP contends that the only document Dr. Rubin relied upon was a print out of adverse drug event reports submitted to the FDA, which was shown to him as part of an ABC News interview. AHP asserts that Dr. Rubin never reviewed the accuracy of this document, nor did he review a single adverse drug event report in formulating his opinion. AHP argues that, in fact, Dr. Rubin does not even have and did not produce a copy of the document; it was merely shown to him.

***4** AHP further argues that Dr. Rubin's opinions will mislead and confuse the jury. Dr. Rubin states that he will opine generally that more information regarding pulmonary hypertension should have been provided. AHP argues that such an opinion will not assist the trier of fact and that further confusion will stem from Dr. Rubin's lack of qualifications and failure to use any methodology regarding the labeling of Pondimin.

Dr. Rubin states that the inadequacies in labeling which he points out are the kind of information prescribing physicians rely upon. AHP, however, asserts that Dr. Rubin does not prescribe appetite suppressants and has done no research concerning what physicians who actually prescribed Pondimin would rely upon in making their decisions. Additionally, AHP argues that Dr. Rubin has no case specific information regarding what a particular prescribing physician knew. In sum, AHP contends that Dr. Rubin's opinions on labeling amount to expressions of personal feeling and are not proper expert testimony.

Plaintiffs respond that AHP improperly characterizes Dr. Rubin's opinions as related to regulations. Plaintiffs assert that the content of a warning must be medically and scientifically accurate and that Dr. Rubin's opinions address the accuracy of AHP's warning. In fact, Plaintiffs point out that AHP retained Dr. Rubin for his expertise in PPH and to develop an algorithm in order to distinguish between PH and PPH. Moreover, Plaintiffs point out that even AHP's own regulatory witness stated that regulatory expertise does not qualify a witness to draft the content of a drug warning.

Plaintiffs also contend that Dr. Rubin relies on good grounds for his opinions. For example, Plaintiffs assert that Dr. Rubin relies on good grounds to support his view that the Pondimin label prior to 1997 was misleading. According to Plaintiffs, these good grounds include: (1) an article in 1993 which reported 15 cases of fatal and irreversible PPH; (2) an AHP line listing shown to Dr. Rubin first by ABC News but later by other attorneys in connection with this case which indicated a number of reported PH cases; and (3) the fact that in August 1996, AHP was aware of at least 62 fenfluramine associated PH cases (including 20 deaths) and 142 additional PH cases associated with dexfenfluramine (including 52 deaths) on a worldwide basis. Plaintiffs further argue that AHP relied on this very same article and AHP line listing to reach the same conclusion internally in 1994, when AHP employees suggested that the Pondimin label was wrong and should be revised.

2. Opinions Regarding Pharmacological Similarities Between Different Drugs Including Aminorex and Pondimin.

Dr. Rubin has referred to the drug Aminorex to support his conclusion that diet drugs cause PPH. Both aminorex fumarate ("Aminorex") and fenfluramine are anorectic agents. (AHP Mot. re: Rubin Ex. A ¶ 12, at 6.) AHP asserts that Dr. Rubin cannot compare these drugs because he is not qualified to give expert opinions in general pharmacology. AHP argues that Aminorex has a different pharmacology from fenfluramine and dexfenfluramine and, thus, cannot be used to show that fenfluramine or dexfenfluramine caused PPH. AHP has had no involvement with Aminorex and asserts that there is nothing in the record to show that any plaintiff in a case where Dr. Rubin is an expert took Aminorex. In addition, AHP contends that Aminorex-related testimony would confuse the jury by creating a mini-trial over the similarities and differences between Aminorex and AHP's products.

***5** Plaintiffs respond that Dr. Rubin does not have to be a pharmacologist to opine that the outbreak of PPH in persons who took Aminorex, an anorexigen, should have put AHP on notice that anorexigens were potentially problematic and should have been investigated thoroughly.

3. Opinions Regarding Corporate Conduct of AHP.

AHP asserts that Dr. Rubin should not be permitted to testify regarding his meetings and communications

with the manufacturers of Pondimin and Redux. Similarly, AHP asserts that Dr. Rubin should be barred from offering opinions on the propriety of AHP's corporate actions. In support of its assertions, AHP argues that Dr. Rubin is not an expert on corporate conduct, has never worked for the FDA and has no understanding of the applicable FDA regulations.

Plaintiffs respond that AHP is seeking exclusion of factual evidence which is not implicated by *Daubert* at all. Plaintiffs also believe that such a blanket request is best left to the transferor courts who can consider the relevance of the proposed evidence in light of the facts of each case based on a fuller record than that which has been developed by AHP in the instant motion.

II. *LEGAL STANDARD*

Federal Rule of Evidence 702 imposes an obligation on a trial judge to " 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.' " [FN9] *Kumho Tire Co ., Ltd. v. Carmichael,* 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharms., Inc.,* 509 U.S. 579, 589 (1993)). The party offering the expert has the burden of proving admissibility under Rule 702. *See Daubert,* 509 U.S. at 592 n. 10 (citing Federal Rule of Evidence 104(a)). In *Daubert,* the Court required that the subject of an expert's testimony must constitute "scientific knowledge." *Id.* at 589-90. "The adjective 'scientific' implies a grounding in the methods and procedures of science," and "the word 'knowledge' connotes more than subjective belief or unsupported speculation." *Id.* at 590. In addition, Rule 702 requires that expert evidence or testimony assist the trier of fact. *See id.* at 591. In other words, expert testimony must "fit" the issues in a case by having a "valid scientific connection to the pertinent inquiry" before the trier of fact. *Id.* at 591-92.

> FN9. The Rule provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed.R.Evid. 702.

Faced with a proffer of expert testimony, the court must determine "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact." *Id.* at 592. In undertaking this gatekeeping function, the court must assess "whether the reasoning or methodology underlying the testimony is scientifically valid" and whether "that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592- 93. In *Daubert,* the Court identified several factors to assist courts in evaluating whether a scientific theory or methodology constitutes reliable scientific knowledge. These include: whether the theory or technique can be or has been tested; whether the theory has been subjected to peer review and publication; whether a technique has a known or potential rate of error and whether there are standards controlling the technique's operation; and whether the theory or method has general acceptance in the scientific community. *See id.* at 593-94 (listing factors which may bear on inquiry, but stating that such factors did not establish definitive checklist or test). The court's role as a gatekeeper is a flexible one and these factors "are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted." *Heller v. Shaw Indus., Inc.,* 167 F.3d 146, 152 (3d Cir.1999).

***6** A court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." 4 Weinstein's Fed. Evid. § 702.06[1], at 702-52 (2000); *see Wehling v. Sandoz Pharms, Corp.,* 162 F.3d 1158 (4th Cir.1998) (available at No. 97-2212, 1998 WL 546097, at * 4 (4th Cir. Aug. 20, 1998)) (stating that pharmacist/toxicologist was unqualified to testify as to adequacy of drug warning where he had "never been involved with the drafting, regulation, or approval of product labeling for any prescription medication" and that "experience as a pharmacist, reading prescription labels and dispensing drugs, [did] not qualify him to testify about the adequacy of drug warnings"); *Robertson v. Norton Co.,* 148 F.3d 905, 907 (8th Cir.1998) (stating that, while ceramics expert "was undoubtedly qualified to testify about a manufacturing defect in an exploding ceramic grinding wheel, that did not qualify him as an expert on grinding wheel warnings," because, among other things, "[h]e had never designed a warning for a ceramic product" and "[h]is knowledge of ceramics would not provide the expertise on questions of display, syntax, and emphasis that the jury would expect from a bona fide warning expert"); *Kent v. Howell Elec. Motors,* No. Civ. A. 96-7221, 1999 WL 517106, at *5 (E.D.Pa. July 20, 1999) (excluding engineering expert from offering opinion as to adequacy of warnings because expert admitted he was not expert in warning design); *Tyler v. Sterling Drug Co.,* 19 F.Supp.2d 1239, 1245 (N.D.Okla.1998)

(excluding testimony of human factors psychologist as to product warnings); *Estate of Lam v. Upjohn Co.*, No. Civ. A. 94-003-H, 1995 WL 478844, at *2 (W.D.Va. April 21, 1995) (recommending exclusion of expert testimony on pharmaceutical warnings when expert had "no academic training or regulatory experience and ha[d] never participated in any FDA-related proceedings addressing what constitutes an adequate warning"). In other words, a party cannot qualify an expert generally by showing that the expert has specialized knowledge or training that would qualify him or her to opine on some other issue. *See Redman v. John D. Brush and Co.*, 111 F.3d 1174, 1179 (4th Cir.1997) (holding that metallurgic expert could testify about properties and characteristics of metal safe, but was not qualified to testify about industry standards for design of safes because "he had never before analyzed a safe, engaged in the manufacture or design of safes, or received any training regarding safes," and, "[e]ven more importantly, he was not personally familiar with the standards ... used in the safe industry"); *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir.1996) (holding that ecologist with expertise in behavior patterns of rats was not qualified to opine on source of chromosomal damage exhibited by rats; nor was he qualified to opine on whether humans faced increased health risks from exposure to chemicals).

***7** In addition, an expert's opinion must be based on scientific, technical or other specialized knowledge and not on "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 590; *see Textron, Inc. v. Barber-Colman Co.*, 903 F.Supp. 1558, 1564 (W.D.N.C.1995) (stating that "not every opinion offered by an expert is an expert opinion ... [and that] an expert's opinion must be an 'expert' opinion (that is an opinion formed by the witness' expertise) rather than simply an opinion broached by a purported expert"). Moreover, testimony of an expert that constitutes mere personal belief as to the weight of the evidence invades the province of the jury. *See McGowan v. Cooper Indus., Inc.*, 863 F.2d 1266, 1273 (6th Cir.1987) (holding that while expert's testimony on industry custom was admissible, "once the jury heard all of the evidence on the scope of [the defendant's] duty, it was as qualified as [the expert] to determine whether [the defendant] breached that duty"); *STX. Inc. v. Brine, Inc.*, 37 F.Supp.2d 740, 768 (D.Md.1999), *aff'd*, 211 F.3d 588 (Fed.Cir.2000), *aff'd*, No. 99-1540, 2000 WL 564010 (Fed.Cir. May 8, 2000) (stating that " 'an expert's opinion on the ultimate legal issue must be supported by something more than a conclusory statement' ') (quoting *In re Buchner*, 929 F.2d 660, 661 (Fed.Cir.1991)); *Securities and Exch. Comm'n v. Lipson*, 46 F.Supp.2d 758, 763 (N.D.Ill.1998) (holding that expert's training and experience as accountant did not "specially equip him to divine what [the defendant] truly believed" about reliability of financial reports and that any opinions offered in that regard were "at worst, speculation [and that] at best, they are credibility choices that are within the province of the jury").

III. *DISCUSSION*

Initially, the court will address some practical concerns that stem from the manner and circumstances under which the instant motions were presented. Then, the court will address the four general subject areas which will encompass the scope of its ruling on these motions: (1) the introduction of documents and other testimony into the preservation depositions of witnesses; (2) the corporate intent of AHP; (3) the opinions rendered by Drs. Avorn and Rubin concerning disciplines in which they are not qualified but that are purportedly offered only to the extent that they put AHP on notice of a particular circumstance; and (4) opinions concerning FDA regulations, drug warnings, drug labels and the thoughts and considerations of physicians generally.

A. *Practical Concerns*

From a practical standpoint, these *Daubert* motions present this MDL transferee court with a unique situation. AHP's challenges to the expert testimony of Drs. Avorn and Rubin arose out of the statements made in response to questions addressed to them at their preservation depositions. The preservation depositions are especially important in the MDL sense, because in most trials before transferor courts, Drs. Avorn and Rubin will not appear live, but will be offered on video to a jury. This presents the court with several concerns involving judicial administration. First, the court recognizes that this testimony will be offered, presumably, at hundreds of trials in different states where the Federal Rules of Evidence will apply. However, the state substantive law applied by these transferor courts may be different (i.e., state laws about informed consent). These differences in state law may affect the substance of a particular civil action as it involves the content of the drug warnings and labels and other issues. The preservation deposition of an expert witness, therefore, must be handled in a materially different way than the preservation deposition of a fact witness. The mechanics of the preparation of the preservation deposition should be such that

depending on transferor court rulings as to relevancy, admissibility, and Rule 403 balancing, excerpts from portions of the preservation deposition--including questions, answers and possibly even exhibits--may have to be deleted or rearranged.

***8** It is impossible to make such adjustments if many of these ideas and thoughts embodied in questions, answers and exhibits are so intertwined that redaction is either impossible, awkward or results in a confusing presentation in what remains of a preservation deposition to present to a jury after editing. Thus, aside from the content that can be a problem depending on where the case will be tried, and before which judge (who will rule on admissibility, relevancy and other factors), the actual structure of the document to be depicted on the video has to be taken into consideration at the time that it is prepared. There is no way for this MDL transferee court to go through these preservation depositions and exclude certain portions and grant AHP's motion in part, but allow other portions and deny AHP's motion in part. Chopping, cutting and pasting would be an arduous task and will probably distort the entire presentation in many portions that are to be conveyed by video.

B. *AHP's Instant Challenges*

Initially, the parties agree that both Dr. Avorn and Dr. Rubin are highly qualified within their particular disciplines. Many of the opinions rendered by these witnesses then, presumably, are not being challenged. Specifically, AHP recognizes that Dr. Avorn is qualified as a pharmacoepidemiologist and pharmacoeconomist and that Dr. Avorn's preservation deposition testimony does address some issues within his expertise. Likewise, AHP recognizes that Dr. Rubin is qualified as an expert on PPH and that his preservation deposition testimony does address some issues within his expertise.

How these witnesses will be presented in the video is another matter and is not before us, but could very well be before trial judges throughout the country. Although those judges will still be governed by the Federal Rules of Evidence there could be differences among them about relevancy, admissibility and Rule 403 balancing. With these concerns in mind, the court finds that AHP's challenges to the testimony of Drs. Avorn and Rubin fall into four categories: (1) the introduction of documents and other testimony into the preservation depositions of witnesses; (2) the corporate intent of AHP; (3) the opinions rendered by Drs. Avorn and Rubin concerning disciplines in which they are not qualified but that are purportedly offered only to the extent that they put AHP on notice of a particular circumstance; and (4) opinions concerning FDA regulations, drug warnings, drug labels and the thoughts and considerations of physicians generally.

1. The Lengthy Introduction of Documents and Other Testimony into the Witness' Preservation Deposition.

Whether a particular document can be introduced through a witness as a basis for his expert opinion will, of course, be left to the trial judge in the transferor court. If the document that is being read or paraphrased to the witness is in fact admitted into evidence (i.e. it is relevant and admissible, and there is no Rule 403 balancing reason to preclude it), presumably the trial judge will allow the witness to speak to it. On the other hand, if it is inadmissible, or if it is capable of being admissible but is irrelevant, or if both admissible and relevant but, pursuant to Rule 403, its prejudice outweighs its probative value, it will not get into evidence and the witness will not be called upon to speak about it. There is no way for this MDL transferee court to predict whether a portion of the preservation deposition should be portrayed to the jury or not. Accordingly, the court cannot and will not grant AHP's motion to preclude it. The time when those issues should be decided is when the trial court, presumably at a pretrial conference, would be called upon to order redaction of certain portions of the video preservation deposition.

2. The Corporate Intent of AHP.

***9** Regarding expert opinions as to AHP's corporate intent, the court finds trouble in the qualifications of both Drs. Rubin and Avorn. The court also finds trouble with the admissibility of an opinion on this subject. Even if such an opinion was relevant, there are serious problems with the reliability of these opinions. The witnesses are qualified in particular scientific disciplines. These disciplines do not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion. If the witnesses' bases for the opinions concerning improper intent come from other evidence such as letters, admissions of AHP officers or employees, or other admissible evidence, *that* is what the jury

should hear and the question of AHP's intent would flow from such evidence to be determined by the jury. *See City of Tuscaloosa v. Harcos Chem. Inc .*, 158 F.3d 548, 565 (11th Cir.1998) (stating that statistician's characterizations of documentary evidence as reflective of collusion would not assist trier of fact through application of scientific, technical or other specialized knowledge to understand evidence or determine fact in issue because "the trier of fact is entirely capable of determining whether or not to draw such conclusions without any technical assistance from ... experts").

The question of intent is a classic jury question and not one for experts, and clearly not these experts. *See e.g., Voilas v. General Motors Corp.*, 73 F.Supp.2d 452, 464 (D.N.J.1999) (stating that area of assessing punitive damages, implicative of various societal policies and lacking any basis in economics "rests strictly within the province of the jury and, thus, does not necessitate the aid of expert testimony"). Thus, to the extent that AHP's motions seek to preclude Drs. Avorn and Rubin from testifying about the corporate intent of AHP, the court will grant the motions.

In doing so, the court specifically notes that its ruling does not preclude Plaintiffs from introducing evidence of the intent of AHP leadership or personnel. In fact, the court recognizes that such evidence could be relevant and, indeed, could be admissible. For example, in a particular civil action, punitive damage claims may bring into play the right of plaintiffs to show what conduct of AHP was in reckless indifference to the health and well-being of persons that were targeted for diet drug consumption by reason of a dominating or overriding policy to maximize profits at any cost. Evidence to that effect may or may not be relevant. A particular plaintiff may choose not to proceed to recover punitive damages for a number of strategic reasons. Other plaintiffs may feel otherwise. If they feel otherwise and make such a claim, evidence of such intent may be considered by the trial court and its admissibility may be challenged on customary grounds or on Rule 403 grounds. It is doubtful that an opinion will be received in that regard from any witness, let alone Drs. Avorn and Rubin, whose specialties are clearly in other fields. For these reasons, the court will grant AHP's motions regarding these witnesses' opinions about AHP's corporate intent and it leaves to another day, and another courtroom, whether evidence of AHP's intent can be presented to the jury and if so to what extent.

3. Opinions Rendered by Drs. Avorn and Rubin Concerning Disciplines in Which They Are Not Qualified But That Are Purportedly Offered Only to the Extent That They Put AHP on Notice of a Particular Circumstance.

***10** Specifically, the court will address Dr. Rubin's preservation deposition testimony regarding Aminorex and Dr. Avorn's preservation deposition testimony agreeing with Colin Bloor, M.D.'s opinion regarding the Servier Rat Slides.

a. Dr. Rubin's Testimony Regarding Aminorex

Dr. Rubin has rendered the opinion that there is an association between anorexigens and primary pulmonary hypertension. (AHP Mot. re: Rubin Ex. A ¶ 11, at 5.) He draws into that opinion the fact that in the 1960's there was an epidemic of PPH in Switzerland, Germany and Austria in association with Aminorex. He goes on to opine that in 1981, case reports of PPH in association with the use of fenfluramine, another anorexigen, began to appear in the scientific literature, and he cites a number of articles. (AHP Mot. re: Rubin Ex. A ¶ 12, at 6.) Dr. Rubin concludes that studies in the 1990's established an association between the use of anorexigens and an increased risk of PPH. (AHP Mot. re: Rubin Ex. A ¶ ¶ 14-16, at 6-7.)

AHP contends that Dr. Rubin has referred to the drug Aminorex to support his conclusion that diet drugs cause PPH. AHP also suggests that all reference to Aminorex should be excluded because of the possibility of the real danger of unfair prejudice, confusion and misleading the jury.

There appears to be good ground to exclude an opinion, if there is one, that because Aminorex has been shown to have a close association with PPH and because fenfluramine is also an anorexigen, albeit with significant pharmacological differences, [FN10] that there is scientific support for the opinion that fenfluramine causes PPH. The court has not been presented with an opinion by Dr. Rubin that supports the notion that all anorexigens including Aminorex and fenfluramine can cause PPH. Indeed, Plaintiffs acknowledge that Dr. Rubin is not a pharmacologist. (Pls.' Opp. to AHP Mot. re: Rubin at 23.)

> FN10. *See* Generic Expert Witness Report of Nancy Balter, M.D.. (AHP Mot. re: Rubin Ex. G ¶ 23, at 12.)

Instead, Plaintiffs argue that Dr. Rubin should at least be able to opine about the Aminorex experience

for the purpose of showing that the scientific community was on notice that anorexigens have long been associated with PPH. This poses a dilemma faced by this MDL transferee court on a *Daubert* challenge to this sort of an opinion. The trial court will have to determine whether or not notice is an issue before the jury. Notice could very well be an issue with a negligence claim, but it would not be so on a strict liability or regulatory violation claim. Indeed, in depth testimony concerning the pharmacological differences may demonstrate that the Aminorex experience of the 1960's vis a vis the fenfluramine experience of the 1990's might bring about exclusion under Rule 403.

At this stage of the litigation, this MDL transferee court concludes that there is no reliable basis for Dr. Rubin to state with a reasonable degree of medical certainty that because Aminorex was determined to have an association with PPH in the 1960's, that fenfluramine can cause PPH in the 1990's and beyond. If there was such an opinion the same should be precluded. However, the court does not understand Plaintiffs to be proffering such an opinion from Dr. Rubin. To the extent that the Aminorex experience in the 1960's may support evidence of notice to the pharmaceutical community, the court will leave that ultimate decision to the trial court.

b. Dr. Avorn's Testimony Regarding Servier Rat Slide Studies

***11** Dr. Avorn agrees with the opinions of Colin Bloor, M.D., a pathologist who examined the Servier Rat Slides. Plaintiffs recognize that Dr. Avorn is not qualified as a pathologist. Instead, Plaintiffs argue that Dr. Avorn should be able to testify about Dr. Bloor's review of the Servier Rat Slide Studies for the purpose of showing that AHP was on notice of the potential need for further investigation of any potential dangers associated with dexfenfluramine. For the same reasons as stated above involving issues of notice with regard to Dr. Rubin's opinions about Aminorex, the court makes the following conclusions. First, there is no reliable basis for Dr. Avorn to opine about pathological issues relating to the Servier Rat Slide Studies. Second, to the extent that the Servier Rat Slide Studies support evidence of notice to AHP of the potential need for further investigation into dexfenfluramine, the court will leave that ultimate decision to the trial court.

4. Opinions Concerning FDA Regulations, Drug Warnings, Drug Labels and the Thoughts and Considerations of Physicians Generally.

AHP seeks to preclude any opinions by these witnesses concerning the drug labeling experience encountered by AHP regarding the diet drugs in question. The parties agree that Drs. Avorn and Rubin are fully qualified within their disciplines and that they can testify concerning risks and benefits of the diet drugs in issue. The parties also agree that these doctors can provide the medical and scientific testimony as it relates to PPH. AHP's objections to Dr. Avorn's and Dr. Rubin's testimony go to the extent to which the labels were, from a regulatory vantage point, proper. AHP also objects to the opinions of these witnesses to the extent that they purport to predict what all doctors take into consideration when they read drug labels in determining whether to prescribe a particular drug.

Dr. Avorn admits that he is not an expert in the regulatory field. (AHP Mot. re: Avorn Ex. B at 46.) While Dr. Rubin has had some contact with labeling concerns and has been involved in the creation of labeling to some extent, it has been somewhat secondary to his primary endeavors within his discipline. Dr. Rubin also admits that he is not an expert in the regulatory field. (AHP Mot. re: Rubin Ex. B at 304-05.) On the present record, therefore, the court concludes that although Drs. Avorn and Rubin are fully qualified within their specialties, that does not qualify them to speak as experts in the field of the requirements of the federal regulations regarding labeling and warnings for FDA approved drugs. In addition, Dr. Rubin's and Dr. Avorn's qualifications do not qualify them to opine as experts about what all doctors generally consider in making prescription decisions.

On the other hand, Dr. Rubin and Dr. Avorn are fully qualified to opine on the medical facts and science regarding the risks and benefits of the diet drugs in question and to compare that knowledge with what was provided in the text of labeling and warnings on the diet drugs in question. In other words, Drs. Rubin and Avorn are qualified to render an opinion as to the labels' completeness, accuracy, and--it follows from that--the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits of the diet drugs in issue are or were at the time the labeling was published. Again, whether or not such an opinion would be admissible will depend on an articulation by the trial judge of the issues to be decided and the law to be applied in that proceeding.

***12** The court can easily preclude, from a *Daubert*

viewpoint, the rendering of opinions by either of these witnesses as to a label's compliance with federal regulatory requirements or as to what doctors in general think, because the witnesses are not qualified for that. However, the court cannot preclude their opinions comparing facts in evidence with the status of the content shown on the labeling of the diet drugs. Indeed, on this topic, state law may have some effect on the extent to which such opinions, though offered by qualified witnesses, may be limited on considerations of relevancy.

IV. *CONCLUSION*

For the foregoing reasons the court will grant in part and deny in part AHP's *Daubert* motions concerning Drs. Avorn and Rubin.

An appropriate Pretrial Order follows.

PRETRIAL ORDER NO. 1332

AND NOW, TO WIT, this 20th day of June, 2000, upon consideration of American Home Products Corporation's Motions to Limit the Expert Testimony of Jerome L. Avorn, M.D. and to Exclude Testimony of Lewis J. Rubin, M.D. and the responses thereto, IT IS ORDERED that said motions are GRANTED IN PART and DENIED IN PART:

1. to the extent that Drs. Avorn or Rubin are proffering opinions concerning the content of third party documents including letters that may not be received in evidence, the motions are GRANTED. To the extent that such documents are received in evidence the determination as to the admissibility of the witnesses' opinions should be determined by the trial court;
2. to the extent that Drs. Avorn and Rubin proffer opinions as to the intent of AHP as evidenced by the words and conduct of their agents, servants or employees, the motions are GRANTED;
3. to the extent that any opinion by Dr. Rubin concerning any connection between Aminorex and the diet drugs in question seeks to support a conclusion that because Aminorex has an association with PPH that the diet drugs at issue have an association and/or a causal connection between their ingestion and PPH, AHP's motion seeking to preclude the expert testimony of Dr. Rubin is GRANTED. This preclusion does not affect the extent to which a trial court may consider the Aminorex experience of the 1960's and events that followed in connection with the investigation or study of Aminorex as a ground to allow an opinion concerning notice to the pharmaceutical community of any association that might have been shown by those events involving Aminorex;
4. to the extent that there is any opinion by Dr. Avorn as to the pathology of the Servier Rat Slide Studies reviewed by Colin Bloor, M.D., AHP's motion seeking to preclude the expert testimony of Dr. Avorn is GRANTED. This preclusion does not affect the extent to which a trial court may consider the Servier Rat Slide Studies as a ground to allow an opinion concerning notice to AHP of the need for further investigation concerning the potential dangers of dexfenfluramine; and
5. to the extent that opinions are proffered by Drs. Avorn or Rubin concerning the extent to which there was legal compliance with any laws or regulations governing the preparation, including the content of labeling or other warnings furnished by AHP in conjunction with the marketing of the diet drugs at issue, the motions are GRANTED.

***13** IT IS FURTHER ORDERED that the extent to which any matters in items 1 through 5 above permits the rendering of opinions by either Drs. Avorn or Rubin, such allowances shall be conditioned upon a determination by the trial court that such matters are relevant and that the evidence upon which any opinion stands be received into evidence at the trial.

2000 WL 876900 (E.D.Pa.)

Motions, Pleadings and Filings **(Back to top)**

- 2001 WL 34134825 (Trial Motion, Memorandum and Affidavit) American Home Products Corporation%7Ds Motion to Enforce Pretrial Order No. 1415 Against Plaintiff Suzanne Jortner (Nov. 05, 2001)

- 2001 WL 34134824 (Trial Motion, Memorandum and Affidavit) Motion of American Home Products Corporation for Order Enforcing Pto 1415 Against Certain Plaintiffs Asserting Settled Claims Under the Guise of Asserting Claims Based on Primary Pulmonary Hypertension (Oct. 19, 2001)

- 2000 WL 34016470 (Trial Motion, Memorandum and Affidavit) American Home Products Corporation%7Ds Opposition to the Dunn Objectors%7D Request for Further Discovery (Nov. 29, 2000)

- 2000 WL 34016465 (Trial Motion, Memorandum and Affidavit) Memorandum of Vinson Carithers, III in Opposition to Class Counsels%7D Motion to Impose Bond Requirement on Certain Objectors for the Filing of an Appeal (Oct. 30, 2000)

• 2000 WL 34016471 (Trial Motion, Memorandum and Affidavit) Memorandum of Vinson Carithers, III in Opposition to Class Counsels%7D Motion to Impose Bond Requirement on Certain Objectors for the Filing of an Appeal (Oct. 23, 2000)

• 2000 WL 34016462 (Trial Motion, Memorandum and Affidavit) Joint Motion for Approval of Fourth Amendment to Nationwide Class Action Settlement Agreement (Aug. 10, 2000)

• 2000 WL 34016441 (Trial Filing) Pretrial Order No. (Jun. 20, 2000)

• 2000 WL 34016442 (Trial Filing) Cigna Healthcare%7Ds Statement of the Issues to be Presented on Appeal (Jun. 09, 2000)

• 2000 WL 34017133 (Trial Filing) Pretrial Order No. 1227 (Apr. 06, 2000)

• 2000 WL 34016457 (Trial Motion, Memorandum and Affidavit) Plaintiffs%7D Memorandum in Response to Defendants%7D Motions to Exclude the Expert Testimny of Paul J. Wellman, Ph.D. and Timony J. Maher, Ph.D. (Feb. 25, 2000)

• 2000 WL 34016440 (Trial Filing) Pretrial Order No. (Feb. 14, 2000)

• 2000 WL 34016448 (Trial Motion, Memorandum and Affidavit) Motion of American Home Products Corporation for a Preliminary Injunction Regarding False and Misleading Communications with Absent Class members Through the Internet Addresses (Jan. 19, 2000)

• 1999 WL 33740480 (Trial Motion, Memorandum and Affidavit) American Home Products Corporation's Objection to Certain Provisions of the Interneuron Settlement Agreement (Feb. 05, 1999)

• 1998 WL 34190446 (Trial Motion, Memorandum and Affidavit) Les Laboratoires Servier's Reply Memorandum of Law in Support of its Motion for Reconsideration and Clarification of PTO 373 (Dec. 16, 1998)

• 1998 WL 34190447 (Trial Motion, Memorandum and Affidavit) Les Laboratoires Servier's Memorandum of Law in Opposition to the PMC's Motion to Compel Discovery (Dec. 14, 1998)

• 1998 WL 34202072 (Trial Motion, Memorandum and Affidavit) Memorandum in Support of Plaintiffs' Opposition to Les Laboratoires Servier's Motion for Reconsideration of Pretrial Order No. 271 (Sep. 22, 1998)

• 1998 WL 34202071 (Trial Motion, Memorandum and Affidavit) Les Laboratoires Servier's Motion for a Reconsideration of Pretrial Order No. 271 (Sep. 21, 1998)

• 1998 WL 34202074 (Trial Motion, Memorandum and Affidavit) Plaintiffs' Memorandum of Points and Authorities in Support of Their Opposition to Defendant, Les Laboratoires Servier's Motion for Protective Order and Stay of All Discovery (Sep. 18, 1998)

• 1998 WL 34202075 (Trial Motion, Memorandum and Affidavit) Les Laboratoires Servier's Motion for a Protective Order for a Temporary Stay of all Discovery Against the Sole Non-U.S. Defendant During the Pendency of its Motion to Dismiss (Aug. 31, 1998)

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